IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GAYLE TERRELL, Plaintiff, v. DAVOL, INC., et al., Defendants.	CIVIL ACTION NO. 13-5074

OPINION

Slomsky, J. **July 30, 2014**

I. INTRODUCTION

This products liability action stems from a hernia-repair surgery that took place in 1996. On August 28, 2013, Gayle Terrell ("Plaintiff") filed a Complaint against Davol, Inc. and C.R. Bard, Inc. ("Defendants"), alleging that their Marlex Mesh product, which was surgically implanted, caused her to suffer various physical and emotional injuries over the years. (Doc. No. 1.) On April 28, 2014, Plaintiff filed a Second Amended Complaint (hereinafter "SAC"). (Doc. No. 19.) On May 14, 2014, Defendants filed a Motion to Dismiss the SAC (Doc. No. 20), and the Motion is now ripe for the Court's disposition.[1]

II. BACKGROUND

The following facts are taken from the SAC and must be accepted as true for purposes of the Motion to Dismiss. On or about June 4, 1996, Plaintiff underwent surgery at Hahnemann

[1] In rendering this Opinion, the Court has considered: the Second Amended Complaint (Doc. Nos. 17, 19), Defendants' Motion to Dismiss (Doc. No. 20), Plaintiff's Response in Opposition (Doc. Nos. 21, 22), and Defendants' Reply (Doc. No. 23). The Court notes that Plaintiff filed duplicate copies of both the SAC and the Response to Defendants' Motion to Dismiss. For the sake of clarity, the Court will refer to the SAC as Doc. No. 19 and the Response as Doc. No. 22.

University Hospital to repair bilateral ventral hernias. (Doc. No. 19 at ¶ 9.) Dr. Delphine Bartsosik performed the surgery and used a Bard Marlex Mesh to repair the hernias. (Id.) After the Marlex Mesh was implanted, Plaintiff began experiencing severe abdominal pain and sought treatment to alleviate her discomfort. (Id. at ¶ 10.) As early as February 3, 1997, Plaintiff went the Emergency Room at Hahnemann for severe diarrhea, dizziness, and vaginal bleeding. (Id. at ¶ 11.) At the time, hospital staff were unable to determine the cause of Plaintiff's abdominal pain. (Id.)

Over the years, Plaintiff received frequent treatment for stomach pains, irritable bowel syndrome, fainting spells, diarrhea, vomiting, cramping, and other symptoms. (Id. at ¶ 13.) On or about August 5, 2011, Plaintiff's doctor ordered a CAT scan, which revealed that there was an abscess in the lower quadrant of Plaintiff's abdomen. (Id. at ¶ 15.) She was immediately admitted to the hospital, and a drain was placed in her abdomen. (Id.) Plaintiff was discharged on August 14, 2011. (Id.)

On August 25, 2011, Plaintiff had a second CAT scan. (Id. at ¶ 16.) Her doctor discovered that another abscess had developed in the lower quadrant of her abdomen. (Id.) Plaintiff was readmitted to the hospital, and her doctor scheduled exploratory surgery to determine the cause of her reoccurring abdominal problems. (Id.) The surgery took place on August 30, 2011. (Id. at ¶ 17.) During the procedure, the surgeons discovered that a piece of polypropylene mesh had densely adhered to her abdominal wall and cecum,[2] which was perforated. (Id.) During the surgery, the doctors removed as much mesh as they could, but some portions of the mesh were so densely incorporated into Plaintiff's abdominal wall that they could not be removed safely. (Id. at ¶ 18.) In order to remove portions of the mesh, the surgeons had

[2] The cecum is a pouch or large, tube-like structure in the lower abdominal cavity that is considered to be the first portion of the large intestine.

to remove Plaintiff's appendix and also performed bowel resection surgery. (Id.) They also determined that e-coli had developed in her system. (Id.)

After this surgery, Plaintiff learned that her persistent medical issues were caused by the implanted Marlex Mesh. (Id. at ¶ 19.) According to Plaintiff, the mesh was unreasonably susceptible to shrinkage and contraction inside the body. (Id. at ¶ 25.) In addition, the product was unreasonably capable of "creep," or the gradual elongation and deformation of the mesh when subjected to prolonged tension. (Id. at ¶ 26.) Despite these risks, Defendants marketed Marlex Mesh as a safe, effective, and reliable medical device. (Id. at ¶ 27.)

Plaintiff alleges that feasible and suitable alternatives existed at the time of her June 4, 1996 surgery to repair hernias, which did not present the same frequency or severity of risks. (Id. at ¶ 31.) She also asserts that in many cases, mesh recipients like herself have undergone extensive medical treatment to remove mesh products which caused similar harm. (Id. at ¶ 35.) Finally, she claims that as a result of the implantation of Marlex Mesh, she has permanent physical injuries as well as significant mental pain and suffering. (Id. at ¶ 39.)

On August 28, 2013, due to her injuries, Plaintiff filed the Complaint against Defendants, alleging strict liability and negligence. (Doc. No. 1.) On November 18, 2013, Defendants filed their first Motion to Dismiss. (Doc. No. 4.) Plaintiff subsequently filed an Amended Complaint on December 12, 2013. (Doc. No. 6.) On December 26, 2013, Defendants filed another Motion to Dismiss (Doc. No. 8), and a hearing on the Motion was held on March 14, 2014. At that time, the Court granted Plaintiff leave to amend the already Amended Complaint. (Doc. No. 15.)

On April 28, 2014, Plaintiff filed her SAC, raising the following claims against Defendants: strict liability – manufacturing defect (Count I); breach of implied warranty of merchantability (Count II); negligent manufacturing (Count III); and negligent failure to warn

(Count IV). (Doc. No. 19.) As noted above, on May 14, 2014, Defendants filed a Motion to Dismiss the Second Amended Complaint in its entirety. (Doc. No. 20.) Plaintiff opposes the Motion. (Doc. No. 22.) For reasons that follow, Defendants' Motion will be granted in part and denied in part.[3]

III. STANDARD OF REVIEW

The motion to dismiss standard under Federal Rule of Civil Procedure 12(b)(6) is set forth in Ashcroft v. Iqbal, 556 U.S. 662 (2009). After Iqbal, it is clear that "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice" to defeat a Rule 12(b)(6) motion to dismiss. Id. at 663. See also Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ethypharm S.A. France v. Abbott Labs., 707 F.3d 223, 231 n.14 (3d Cir. 2013) (citing Sheridan v. NGK Metals Corp., 609 F.3d 239, 262 n.27 (3d Cir. 2010)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. Applying the principles of Iqbal and Twombly, the Third Circuit in Santiago v. Warminster Twp., 629 F.3d 121 (3d Cir. 2010), set forth a three-part analysis that a district court in this Circuit must conduct in evaluating whether allegations in a complaint survive a 12(b)(6) motion to dismiss:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." Finally, "where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief."

[3] The two previously filed Motions to Dismiss challenging the claims made in the Complaint and the Amended Complaint were dismissed without prejudice as moot, in view of the subsequent filing of the amended Complaints.

Id. at 130 (quoting Iqbal, 556 U.S. at 675, 679). "This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged." Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011). A 12(b)(6) motion should only be granted if, "'accepting as true the facts alleged and all reasonable inferences that can be drawn therefrom' there is no reasonable reading upon which the plaintiff may be entitled to relief." Vallies v. Sky Bank, 432 F.3d 493, 494 (3d Cir. 2006) (quoting Colburn v. Upper Darby Twp., 838 F.2d 663, 665-66 (3d Cir. 1988)).

A complaint must do more than allege a plaintiff's entitlement to relief, it must "show" such an entitlement with its facts. Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (citing Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234-35 (3d Cir. 2008)). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged — but it has not 'shown' — 'that the pleader is entitled to relief.'" Iqbal, 556 U.S. at 679. The "plausibility" determination is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id.

IV. ANALYSIS

A. The Strict Liability Claim Based on an Alleged Manufacturing Defect Will be Dismissed Because This Claim is Barred Under Pennsylvania Law

In Count I of the SAC, Plaintiff alleges that the Marlex Mesh, when placed into the stream of commerce, contained "manufacturing defects which rendered [the] Marlex Mesh unreasonably dangerous." (Doc. No. 19 at ¶ 43.) According to Plaintiff, the manufacturing defects occurred while the product was in the Defendants' possession, and the defects existed before the mesh left their control. (Id.) As a result, Plaintiff contends that Defendants should be

held strictly liable for the injuries she has suffered. (Id. at ¶ 1.) Defendants argue that this claim should be dismissed because under Pennsylvania law, a strict products liability claim for a defective medical device may not be pursued. (Doc. No. 20-1 at 3.)

Section 402A of the Restatement (Second) of Torts governs strict products liability claims in Pennsylvania.[4] Webb v. Zern, 220 A.2d 853, 854 (Pa. 1966); Mazur v. Merck & Co., 964 F.2d 1348, 1353 (3d Cir. 1992). Comment k to §402A provides as follows:

> There are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous . . . The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

[4] In this case, neither party disputes that the Restatement (Second) of Torts applies. However, the continued viability of the Restatement (Second) has recently been called into question. Since 2009, the Third Circuit has repeatedly predicted that Pennsylvania will adopt the Restatement (Third) of Torts. See Sikkelee v. Precision Airmotive Corp., No. 12-8081, 2012 WL 5077571 (3d Cir. Oct. 17, 2012); Covell v. Bell Sports, Inc., 651 F.3d 357 (3d Cir. 2011); Berrier v. Simplicity Mfg., Inc., 563 F.3d 38 (3d Cir. 2009). The Pennsylvania Supreme Court has yet to do so, and courts within the Commonwealth continue to apply the Restatement (Second).

On March 26, 2013, the Pennsylvania Supreme Court granted allocator in Tincher v. Omega Flex, Inc. to answer the following question:

> Whether this Court should replace the strict liability analysis of Section 402A of the Second Restatement with the analysis of the Third Restatement . . . [and] whether, if the Court were to adopt the Third Restatement, that holding should be applied prospectively or retroactively.

64 A.3d 626, 626-27 (Pa. 2013). No decision has yet been rendered in Tincher. Given this fact, and the fact that the parties do not dispute that the Restatement (Second) governs, the Court will not apply the Restatement (Third). However, in the event that the Pennsylvania Supreme Court adopts the strict liability analysis of the Restatement (Third) of Torts, this Court will entertain a motion for reconsideration if either party concludes that the result would be different.

Restatement (Second) Torts § 402A, cmt. k. In Hahn v. Richter, the Pennsylvania Supreme Court considered whether a prescription drug used to treat back pain was defective[5] because its manufacturer failed to provide sufficient warnings. 673 A.2d 888, 889 (Pa. 1996). The Court in Hahn declined to correct the trial court's decision not to instruct the jury on a theory of strict liability and, as a result, extended §402A's bar on certain strict liability claims to prescription drugs. Id. at 889. In Hahn, the Court held as follows:

> Comment k, titled "Unavoidably unsafe products," denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.

Id. at 889-90. Since Hahn, Pennsylvania courts have barred strict liability claims based on prescription drug defects. While the Pennsylvania Supreme Court has yet to decide whether the Hahn rule equally applies to prescription medical devices, the Superior Court of Pennsylvania has stated that there is "no reason why the same rational [sic] applicable to prescription drugs may not be applied to medical devices." Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006). Federal district courts have reached the same conclusion.[6]

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[5] There are three types of product defects that are recognized in Pennsylvania: (1) design defect, (2) manufacturing defect, and (3) a failure to warn. Parkinson v. Guidant Corp., 315 F.Supp.2d 741, 746 (W.D. Pa. 2004) (citing Phillips v. A-Best Prods. Co., 665 A.2d 1167, 1170 (Pa. 1995)).

[6] Geesey v. Stryker Corp., No. 09-2988, 2010 WL 3069630, *4 (E.D. Pa. Aug. 4, 2010) ("numerous district courts applying Pennsylvania law have predicted that the Pennsylvania Supreme Court will extend comment k to medical devices"); Soufflas v. Zimmer, Inc., 474 F.Supp.2d 737, 750 (E.D. Pa. 2007) (found that the Pennsylvania Supreme Court would extend Section 402A to medical devices); Davenport v. Medtronic, Inc., 302 F.Supp.2d 419, 442 (E.D. Pa. 2004) ("numerous courts in the Eastern District of Pennsylvania have predicted that the Pennsylvania Supreme Court will follow its reasoning in Hahn and hold that prescription medical devices are not covered by Section 402A"); Murray v. Synthes U.S.A., Inc., No. 95-7796, 1999 WL 672937, *7 (E.D. Pa. Aug. 23, 1999) ("this Court predicts that the Pennsylvania Supreme Court will determine, pursuant to its reasoning in Hahn, that prescription medical devices are likewise not covered by Section 402A"); Taylor v. Danek Medical, Inc., No. 95-

As recently as January 2014, the Pennsylvania Supreme Court reiterated this longstanding principle in Lance v. Wyeth, explaining that "for policy reasons, this Court has declined to extend strict liability into the prescription drug arena." 15 A.3d 434, 453 (Pa. 2014). One Superior Court judge has succinctly described the policy reasons as follows:

> [P]ublic policy is best served by not applying the doctrine of strict liability to prescription drugs. Prescription drugs are inherently dangerous products which benefit society . . . A rule of law which held a pharmaceutical company bound for unforeseeable reactions to their products, notwithstanding the FDA's significant oversight of a drug's approval, would stifle the incentive to produce new products . . . Accordingly, the relevant inquiry is and should be the reasonableness of a pharmaceutical company's conduct, as a pharmaceutical manufacturer should not be the insurer against all possible consequences in light of the policy considerations.

Hahn v. Richter, 628 A.2d 860, 871 (Pa. Super. Ct. 1993) (emphasis added) (Cavanaugh, J., concurring), aff'd, 673 A.2d 888 (Pa. 1996); See also Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984) ("[A]ssuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk.").

In accordance with Pennsylvania law, federal district courts have held that in the case of prescription drugs and devices, strict liability claims based on all three defective conditions, including manufacturing defects, are barred in Pennsylvania.[7] For example, in Parkinson v.

7232, 1998 WL 962062, *7 (E.D. Pa. Dec. 29, 1998) ("this Court predicts that the Pennsylvania Supreme Court will determine, pursuant to its reasoning in Hahn, that prescription medical devices are likewise not covered by Section 402A").

[7] See Kee v. Zimmer, Inc., 871 F.Supp.2d 405, 410 (E.D. Pa. 2012) ("[A]ctions for harm caused by prescription medical devices must proceed on a theory of negligence."); Horsmon v. Zimmer Holdings, Inc., No. 11-1050, 2011 WL 5509420, *2 (W.D. Pa. Nov. 10, 2011) ("Hahn is the law of Pennsylvania, and the court in Hahn did not recognize this caveat in Comment k"); Geesey, 2010 WL 3069630 at *5 (dismissing a strict liability claim based on a manufacturing defect); Soufflas, 474 F.Supp.2d at 750 (granting summary judgment for all three defective conditions of strict liability including manufacturing defect for a medical device used to repair knee

Guidant Corp., the court granted summary judgment on the plaintiff's strict products liability claims, interpreting the reach of comment k as follows:

> While comment K precludes strict liability, it does contain the following two caveats for unavoidably unsafe products: "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." However, the Pennsylvania Supreme Court has ruled that §402A strict liability is precluded entirely for prescription drugs, and, presumably by extension, prescription medical devices. Instead, the caveats in comment K are to be evaluated under negligence not strict liability principles.

315 F.Supp.2d 741, 747 (W.D. Pa. Mar. 22, 2004).

In this case, to overcome the § 402A bar on strict liability claims for prescription medical devices, Plaintiff contends that Hahn does not prevent strict liability claims based on manufacturing defects. (Doc. No. 22 at 8.) This Court does not agree. Although federal courts are currently split on this issue of whether § 402A applies to medical devices, and some allow strict liability claims to proceed when a manufacturing defect is alleged,[8] the decisions of these

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instability); Parkinson, 315 F.Supp.2d at 748 n.6 ("the Pennsylvania Supreme Court unambiguously has held that § 402A strict liability does not apply in any way to prescription drugs"); Davenport, 203 F.Supp.2d at 441 ("In Hahn, the Supreme Court of Pennsylvania made clear that 402A is inapplicable to prescription drugs.").

[8] See Kline v. Zimmer Holdings, Inc., No. 13-513, 2013 WL 3279797, *5 (W.D. Pa. June 27, 2013) (citing Dougherty v. C.R. Bard, Inc., No. 11-6048, 2012 WL 2940727 (E.D. Pa. July 18, 2012) to support the principle that comment k does not preclude strict liability claims based on manufacturing defects); Bergstresser v. Bristol-Myers Squibb Co., No. 12-1464, 2013 WL 1760525, *3 (M.D. Pa. April 24, 2013) ("any strict liability claim[s] brought by the plaintiff for failure to warn or design defect are barred by Hahn and its progeny . . . to the extent that the plaintiff attempts to bring a strict liability claim based upon a manufacturing defect, this claim would not be barred"); Tatum v. Takeda Pharmaceuticals North America, Inc., No. 12-1114, 2012 WL 5182895, *2 (E.D. Pa. Oct. 19, 2012) ("this Court agrees with the decision in Dougherty, where the court concluded that strict liability claims for manufacturing defects are not prohibited"); Killen v. Stryker Corp., No. 11-1508, 2012 WL 4498865, *4 (W.D. Pa. Sept. 28, 2012) (citing Dougherty to support denial of a motion to dismiss the plaintiff's strict liability claim for a manufacturing defect); Dougherty, 2012 WL 2940727 at *2 (E.D. Pa. July 18, 2012) (distinguishing Hahn on the basis that strict liability claims involving a manufacturing defect in prescription drug and device cases are not clearly barred in Pennsylvania).

courts pre-date Lance. There, the Pennsylvania Supreme Court reiterated the principle that a strict liability claim based on a defective prescription drug is barred. Lance, 15 A.3d at 453. In explaining this principle, the Court did not exempt from this bar a claim based on a manufacturing defect. Based on the above, this Court predicts that the Supreme Court of Pennsylvania would come to the same conclusion with respect to defective medical devices.

The case before this Court is based on diversity of citizenship jurisdiction, and the Court is bound to follow what it predicts Pennsylvania law will be. Thus, Plaintiff cannot maintain a strict liability claim based on a manufacturing defect in producing a medical device, and Count I of the SAC will be dismissed.

B. The Breach of Implied Warranty of Merchantability Claim Will Be Dismissed Because This Claim is Barred Under Pennsylvania Law

In Count II of the SAC, Plaintiff alleges that Defendants "implicitly warranted that the [Marlex Mesh] was of merchantable quality and fit for the ordinary purpose for which it was intended." (Doc. No. 19 at ¶ 48.) Plaintiff contends that Defendants breached this warranty by issuing her a defective product. (Id. at ¶ 51.) Defendants submit that this claim should be dismissed because this type of claim is also barred by Pennsylvania law. (Doc. No. 20-1 at 6.)

In Makripodis by Makripodis v. Merrell-Dow Pharms., Inc., the Pennsylvania Superior Court held that breach of implied warranty claims for prescription drugs should be treated in the same manner as strict liability claims—precluded under comment k of §402A.[9] 523 A.2d 374, 376-77 (Pa. Super. Ct. 1987). In Makripodis, the plaintiff asserted breach of implied warranty of merchantability and strict liability claims against the manufacturer of a prescription drug that she claimed caused congenital abnormalities to her child after she ingested the drug during

[9] As explained in note 4, supra, the Court is applying the Restatement (Second).

pregnancy. Id. at 375. The court granted summary judgment for the manufacturer on both claims, dismissing the breach of implied warranty of merchantability on the following grounds:

> The essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used . . . the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for "ordinary purposes," as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient.

Id. at 376-77. See also Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 783 (R.I. 1988) ("We recognize that strict liability and implied warranty of merchantability are parallel theories of recovery, one in contract and the other in tort."). Accord Williams v. West Penn Power Co., 467 A.2d 811, 815 n.16 (Pa. 1983) (indicating that, while strict liability claims addressed by §402A and breach of the implied warranty of merchantability addressed by the Uniform Commercial Code are not identical, they are "co-extensive").

Although the Pennsylvania Supreme Court has yet to rule on the viability of a breach of implied warranty of merchantability claim for prescription drugs or medical devices, many federal courts have followed the approach in Makripodis and dismissed breach of implied warranty of merchantability claims for much the same reason that strict liability claims are precluded.[10] As one district court stated:

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[10] See Kee, 871 F.Supp.2d at 409 n.3 (granting motion to dismiss an implied warranty claim arising from harm caused by a medical device implanted during knee surgery); Horsmon, 2011 WL 5509420 at *3 ("Several courts have extended the reasoning of Makripodis to preclude claims against medical device manufacturers for breach of implied warranties of merchantability"); Kester v. Zimmer Holdings, Inc., No. 10-0523, 2010 WL 2696467, *11 (W.D. Pa. June 16, 2010) ("As with strict products liability claims . . . , Pennsylvania courts have held that the nature of prescription drugs and prescription medical devices precludes claims for breach of implied warranty."); Soufflas, 474 F.Supp.2d at 752 (granting summary judgment for the manufacturer of a medical device used to manage knee pain on the basis of an implied warranty claim); Parkinson, 315 F.Supp.2d at 753 ("As breach of implied warranty claims for prescription drugs are precluded under Pennsylvania law, breach of implied warranty claims for prescription medical devices also precluded for identical reasons.");

> In a claim for breach of implied warranty of merchantability, "[t]he essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used." Makripodis v. Merrell–Dow Pharms., Inc., 361 Pa.Super. 589, 523 A.2d 374, 376 (Pa. Super. Ct.1987) (citing Wisniewski v. Great Atl. & Pac. Tea Co., 226 Pa.Super. 574, 323 A.2d 744, 746–47 (Pa. Super. Ct.1974); 13 Pa.C.S. § 2314(b)(3)). Under Pennsylvania law, "the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for ordinary purposes, as each individual for whom they are prescribed is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." Id. at 377, 323 A.2d 744. Breach of implied warranty of merchantability claims, therefore, are precluded for prescription drugs. Id.

Horsmon v. Zimmer Holdings, Inc., No. 11-1050, 2011 WL 5509420, *2 (W.D. Pa. Nov. 10, 2011). This Court predicts that the Supreme Court of Pennsylvania would come to the same conclusion with respect to medical devices.

Despite this prevalent authority, this Court recognizes that just as federal district courts are split regarding strict liability claims based on defects in the manufacture of prescription drugs, there is also a split in authority on the applicability of breach of implied warranty of merchantability claims based on defects in the manufacture of medical devices. Needless to say, Plaintiff would have this Court hold that the breach of an implied warranty of merchantability claim is a viable cause of action under Pennsylvania law, "to the extent [that it is] based on a manufacturing defect."[11] (Doc. No. 22 at 8.) Once again, this Court does not agree with

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Davenport, 302 F.Supp.2d at 442 ("Similar to the reasoning in Hahn relating to application of Section 402A, 'Pennsylvania courts have held that the nature of prescription drugs also precludes claims for breach of the implied warranty of merchantability'"); Murray, 1999 WL 672937 at *9 (recognizing that Makripodis bars breach of implied warranty claims based on medical devices); Taylor, 1998 WL 962062 at *14 ("Because Pennsylvania does not recognize strict liability claims for prescription medical products . . . this Court predicts that the Pennsylvania Supreme Court would exclude a cause of action based on the implied warranty of merchantability for prescription medical devices.").

[11] See Bergstresser, 2013 WL 1760525 at *4 ("[A]ny claim by the plaintiff under a theory of breach of implied warranty of merchantability . . . would be barred under Pennsylvania law to the extent that they are based on a design defect or failure to warn, but would be allowed if

Plaintiff's position. The same reasons discussed above that preclude strict liability claims involving medical devices would apply to breach of implied warranty of merchantability claims. Therefore, Count II of Plaintiff's Second Amended Complaint will also be dismissed.

C. The Negligent Manufacturing Claim is Sufficiently Pled and Will Not Be Dismissed

In Count III of the SAC, Plaintiff asserts a negligent manufacturing claim. (Doc. No. 19 at ¶ 56.) In order for Plaintiff to prove a negligent manufacturing claim, she must show that "(1) the manufacturer owed a duty to the plaintiff, (2) the duty was breached and (3) such a breach was the proximate cause of plaintiff's injuries." Soufflas v. Zimmer, Inc., 474 F.Supp.2d 737, 753 (E.D. Pa. 2007) (citing Phillips v. Cricket Lighters, 841 A.2d 1000, 1008 (Pa. 2003)). Defendants do not contest the first element in their Motion to Dismiss. The second and third elements are in dispute, however.

To demonstrate a breach to satisfy the second element, Plaintiff must show that Defendants "failed to exercise due care in manufacturing or supplying the product. Put another way, Plaintiff must come forward with evidence that [Defendants] . . . deviated from the general standard of care expected under the circumstances." Id. at 754 (citing Taylor v. Danek Medical, Inc., No. 95-7232, 1998 WL 962062, *11 (E.D. Pa. Dec. 29, 1998). More specifically:

> [G]enerally a "manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line" . . . The "manufacturing defect" theory posits that "a suitable design is in place, but that the manufacturing process has in some way deviated from that design."

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based on a manufacturing defect."); Tatum, 2012 WL 5182895 at *3 (reasoning that, as manufacturing defects in prescription drugs and devices are not precluded by comment k under a strict liability theory, breach of implied warranty of merchantability claims possess the same manufacturing defect exception); Dougherty, 2012 WL 2940727 at *7 ("[B]ecause I have concluded that Pennsylvania law does not preclude a strict liability claim based on a manufacturing defect, I see no basis for declining to recognize a claim for breach of the implied warranty of merchantability where it is based on a manufacturing defect.").

Lucas v. City of Visalia, 726 F.Supp.2d 1149, 1154-55 (E.D. Cal. 2010) (internal quotations omitted). See also Phillips, 841 A.2d at 1019 (Saylor, J., concurring) (explaining that manufacturing defects "are deemed present when a product fails to conform to its intended design").

Defendants argue that Plaintiff's negligent manufacturing defect claim should be dismissed because the SAC only contains conclusions in support of her claim and therefore does not meet the pleading standards of Twombly and Iqbal. (Doc. No. 20-1 at 6.) Defendants specifically challenge the negligent manufacturing claim on the grounds that the SAC "does not explain how the Mesh differed from product specifications, how Plaintiff's Mesh deviated from other Marlex Mesh or how any alleged deviation caused Plaintiff's injury." (Id. at 7.)

Defendants rely on Lucas in support of their argument that this claim must be dismissed because it is inadequately pled. In Lucas, a man with a history of seizures was injured when police shocked him with a stun gun or Taser. 726 F.Supp.2d at 1151. The court dismissed the man's claims based on manufacturing and design defects, stating:

> The problem with [Plaintiff's] allegation is that it simply tracks the general elements of strict products liability and contains no pertinent factual allegations. "What is conspicuously absent from these claims is an identification of what aspect of the [product] makes [its] design," or manufacture, defective . . . If [Plaintiff] intends to allege a manufacturing defect, he must identify/explain how the [product] either deviated from [Defendant]'s intended result/design or how the [product] deviated from other seemingly identical [product] models. A bare allegation that the [product] had "a manufacturing defect" is an insufficient legal conclusion . . . Dismissal of [the manufacturing defect claim] is appropriate because the complaint contains no factual allegations that identify what aspect of the subject [product] design and manufacture made it defective.

Id. at 1155-56 (internal quotations omitted).

Defendants also rely on Dilley v. C.R. Bard, Inc., No. 14-1795, 2014 WL 1338877 (C.D. Cal. Apr. 3, 2014), in which the district court dismissed a plaintiff's claims based on

manufacturing and design defects on the grounds that they were insufficiently pled. Id. at *1. There, the plaintiff claimed that medical repair mesh was negligently manufactured and alleged that "defendants' Perfix mesh plugs and patches possessed a defect in their manufacture that caused them to shrink, harden, and scarify . . . ." Id. at *3. The court found this allegation to be inadequate because it did not explain how the product deviated from the manufacturer's intended design. Id.

In her SAC, Plaintiff alleges three main facts in order to support her negligent manufacturing claim. First, she asserts that Defendants failed "to manufacture the Mesh in a sterile fashion." (Doc. No. 19 at ¶ 56.) Second, they failed "to manufacture the Mesh in accordance with product specifications." (Id.) Third, Defendants failed "to manufacture the Mesh consistent with product design." (Id.) Like the insufficient pleadings in Lucas and Dilley, the last two allegations of Plaintiff's Second Amended Complaint are too vague and unspecific to survive a motion to dismiss. These assertions merely track elements of a manufacturing defect claim without providing any factual support.

Plaintiff's assertion, however, that Defendants failed "to manufacture the Mesh in a sterile fashion" is sufficient to satisfy the Iqbal and Twombly pleading standards. (Id.) Accepting Plaintiff's allegation as true at this stage of the litigation, it is plausible that this particular product deviated from its intended design because it was not sterile when it left Defendants' control. Thus, Plaintiff has satisfied the second element of a negligent manufacturing claim.

A review of the SAC also reveals that Plaintiff has satisfied the third element of this claim, alleging facts which make it plausible that the unsterilized mesh proximately cause her injuries. For example, Plaintiff alleges that following the implantation of the Marlex Mesh, she

began experiencing severe abdominal pains and was consistently treated by physicians to alleviate her discomfort. (Doc. No. 19 at ¶ 10.) Plaintiff continued to suffer abdominal pain until she underwent surgery in August 2011. During that procedure, doctors discovered that e-coli had developed in her system. (Id. at ¶ 18.) These allegations, and those involving other ailments that plagued Plaintiff, could have resulted from the allegedly unsterile Marlex Mesh. It is therefore plausible that the Marlex Mesh proximately caused Plaintiff's injuries. For these reasons, the Court will not dismiss Count III of the SAC.[12]

D. The Negligent Failure to Warn Claim is Sufficiently Pled and Will Not be Dismissed

In Count IV of the SAC, Plaintiff asserts a claim for a negligent failure to warn. (Doc. No. 19 at ¶ 60.) Under Pennsylvania law, manufacturers may be held liable for failing to warn consumers about the dangers associated with their products. However, in the case of prescription drugs and devices, a manufacturer's duty to warn is governed by the "learned intermediary doctrine." Baldino, 478 A.2d at 812. Specifically, "the duty of a drug manufacturer to warn of the possible dangers and side effects of prescription drugs runs to the physician, and not to the patient or to the general public." Kline v. Pfizer, Inc., No. 08-3238, 2008 WL 4787577, *3 (E.D. Pa. Oct. 31, 2008) (citing Baldino, 478 A.2d at 812). See also Makripodis, 523 A.2d at 378 ("[T]he warnings, which are required to be given by the manufacturer must be directed to the physician, not the patient-consumer."). A plaintiff will succeed on this type of failure to warn claim if she can prove that "had defendant issued a proper warning to the learned intermediary,

[12] While the claims involving the failure to manufacture the Mesh in accordance with its product design and specifications are unsupported allegations at this stage, Plaintiff has the option of seeking leave to amend the SAC if during discovery she uncovers factual support for these claims. Moreover, the Court will permit discovery on these claims because to some extent, they overlap with the assertion that the Mesh was manufactured in a non-sterile fashion. Product design and specifications are relevant to this claim.

he would have altered his behavior and the injury would have been avoided." Mazur v. Merck & Co., Inc., 742 F.Supp. 239, 262 (E.D. Pa. 1990).

Plaintiff alleges in the SAC that Defendants failed "to provide adequate warnings and instructions to Plaintiff's physicians regarding the Marlex Mesh." (Doc. No. 19 at ¶ 60.) Therefore, the issue to be determined in this case is "whether the warning, if any, that was given to the prescribing physicians was proper and adequate." Makripodis, 523 A.2d at 378. Defendants argue that Plaintiff's negligent failure to warn claim should be dismissed because the "bald allegation" in the SAC does not set forth a plausible negligent failure to warn claim. (Doc. No. 23 at 2.)

Defendants rely on Bergstresser v. Bristol-Myers Squibb Co., No. 12-1464, 2013 WL 6230489, *4 (M.D. Pa. Dec. 2, 2013), in support of their argument. (Doc. No. 20-1 at 7-8.) There, after affording the plaintiff an opportunity to amend his complaint, the district court granted the defendant's motion to dismiss a negligent failure to warn claim, reasoning that the plaintiff still had not cured the deficiencies in his original complaint. Specifically, the plaintiff failed to identify what the product label actually said and how the label was inadequate. Bergstresser, 2013 WL 6230489 at *4. In reaching this conclusion, the court stated:

> The plaintiff cannot in a conclusory manner simply allege that his injury would not have resulted if his physician was [sic] provided with some unspecified information. He must provide sufficient factual allegations as to why the information provided to the intermediary was inadequate, what information should have been provided, and how that information would have caused the intermediary to act differently.

Id. at *8 (emphasis added).

In the SAC, Plaintiff specifically asserts what information should have been given to her medical providers, setting forth an extensive list. (Doc. No. 19 at ¶ 63.) Unlike the plaintiff in Bergstresser, Plaintiff here is not asserting some "unspecified information" of which Defendants

should have warned her medical providers. Instead, Plaintiff listed a number of specific defects and risks about which Defendants failed to warn Plaintiff's medical providers.[13] In terms of how this information would have caused Plaintiff's medical providers to act differently, Plaintiff alleges that "but for Defendant's [sic] failure to warn, Plaintiff's medical professionals would not have used the Marlex Mesh in The Procedure." (Doc. No. 19 at ¶ 64.)

While Plaintiff fails to explicitly state why the warnings given to her medical providers were inadequate, in viewing the allegations in the light most favorable to her, the Court must infer at this stage that the Marlex Mesh packaging did not include the specific information that Plaintiff identified. Because Plaintiff has listed specific information that she contends should have accompanied Defendants' product, it is plausible that the warnings that were provided were inadequate because they did not include this information and therefore did not fully apprise physicians about the risks associated with this specific device. For these reasons, the Court will not dismiss Count IV of the SAC.

V. CONCLUSION

For the aforementioned reasons, Defendants' Motion to Dismiss the Second Amended Complaint will be granted in part and denied in part. Counts I and II of the Second Amended Complaint will be dismissed. Counts III and IV will not be dismissed at this time. An appropriate Order follows.

[13] For example, Plaintiff mentions the Mesh's tendency to shrink or contract inside the body, to fragment and creep from its place of origin, and its inelasticity and erosive quality. Plaintiff also references greater risks from the Mesh of contracting chronic inflammation, chronic infections, permanent scarring and severe pain, especially in comparison to other feasible alternatives to repair hernias with less risk. In addition, she also lists as attendant risks, the potential for corrective surgery, the difficulty of future repair, the fact that removal of the Mesh may require multiple surgeries, and that complete removal of the Mesh may be impossible. (Doc. No. 19 at ¶ 63.)